K023045

SEP 26 2002

E 510(k) Summary

Trade Name:	MICRORUPTOR V
Common Name:	Q-switched Nd:YAG laser
Classification Name:	Nd:YAG laser for posterior Capsulotomy Peripheral Iridotomy and Pupillary Membranotomy
Predicate Device:	A.R.C. Q-las 10 (k001511)

Description:

The MICRORUPTOR V is a Q-switched Nd:YAG laser system designed for use in ophthalmologic procedures. It has the form of a table containing supply and control electronics and supporting a headrest where the head of the patient is placed, as well as a movable housing that is controlled by a joystick. The housing comprises a biomicroscope with a slit-lamp illumination (Haag-Streit), a Q-switched Nd:YAG laser, a laser diode producing a red (635 nm) aiming beam and optical, mechanical and electronics elements necessary to control the parameters and geometry of the laser beams.

The integrated Q-switched Nd:YAG laser emits short pulses of light at wavelength of 1064 nm. This light is focused in the plane of observation of the ophthalmic microscope. The irradiance at the focal point is high enough to cause optical breakdown, thus permitting the disruption of tissues.

The MICRORUPTOR V allows the physician to adjust the energy delivered to the target tissue and to precisely control and visualize the position of the beam focus, thus allowing a precise and noninvasive dissection of tissues inside the eye of the patient.

Intended Use:

The intended use for the MICRORUPTOR V is for noninvasive tissue/membrane dissection (photodisruption) in the eye. Indications for use include posterior capsulotomy, peripheral iridotomy. and pupillary membranotomy

Technological Characteristics:

The "new" device and the predicate both target the same applications of noninvasive tissue disruption in the eye, including posterior capsulotomy, peripheral iridotomy and pupillary membranotomy . The controls, materials, method of manufacture, indications and labeling of both systems are identical or equivalent.

The "new" device and the predicate consist of a power module, a control module, an ophthalmic microscope with headrest and slit lamp, a laser module and delivery optics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2002

Meridan AG
c/o Mr. Mark Job
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K023045
Trade/Device Name: Microruptor V
Regulation Number: 886.4392
Regulation Name: Nd:YAG laser for posterior capsulotomy and peripheral iridotomy
Regulatory Class: II
Product Code: LXS
Dated: September 6, 2002
Received: September 12. 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D Indications for Use

Applicant: MERIDIAN Inc.
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Phone +41 33 334 11 11
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510(k) Number (if known): K023045

Device Name: MICRORUPTOR V

Indications for Use:

This device will be used in ophthalmic applications, including:

- Posterior Capsulotomy
- Peripheral Iridotomy
- Pupillary Membranectomy

This device is intended for use by skilled Physicians and Healthcare Workers and may only be used under the supervision of a Physician.

" Federal law restricts this device to sale by or on the order of a licenced practioner "

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K023045